

REMARKS

Claims 1, 4-6, 16, 94, 95, and 97-99 were pending. Claim 99 has been canceled and incorporated into claims 1, 4, 5, and 95. Claim 6 has also been canceled. Applicants respectfully request entry of the amendment because it either renders the claims allowable or puts the claims in a better position for appeal. Upon entry of this response claims 1, 4, 5, 16, 94, 95, 97, and 98 are subject to examination. No new matter has been added. Applicants note that claim 9 was previously canceled and is no longer pending. Applicants expressly reserve the right to present additional claims in further applications. Any and all amendments and cancellations are made without prejudice or disclaimer.

35 U.S.C. 112, First Paragraph, Enablement Requirement

Claim 99 stands rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the enablement requirement. The office alleges that the present application does not reasonably enable one of skill in the art at the time the present application was filed to use the methods to treat autosomal recessive retinitis pigmentosa or congenital stationary night blindness by RNA interference of a target gene without resorting to “substantial *de novo* trial and error experimentation with no assurance of ever reaching a successful conclusion.” (Office Action, page 5). The Office alleges that there is “no evidence remotely connecting the treatment of autosomal recessive retinitis pigmentosa or congenital stationary night blindness by inhibiting the expression of any gene and no direction or guidance as to how to achieve the claimed effectiveness other than a general invitation to try.” (Office Action, page 5). The Office also alleges that the present application does not describe any interfering RNAs that can be used or identify or name a “credible target gene” that should be used for the design of the interfering RNAs. Applicants respectfully disagree.

The presently claimed invention is enabled. The Office has failed to carry its burden to show that the presently claimed invention is not enabled. The Office has not carried its burden because the Office has failed to provide sufficient evidence to question the enablement of the presently claimed invention. For example, the Office alleges that the application does not name a “credible target gene.” The Office’s characterization is incorrect. The present application provides sufficient guidance of specific genes that can be targeted. For example, at paragraph

[0097] of the published application two specific genes are specifically identified. The Office alleges that the suppression of these targets using RNA interference is not credible because of other references that allegedly suggest suppression would exacerbate autosomal recessive retinitis pigmentosa or congenital stationary night blindness. However, the Office has not provided any evidence to support this conclusion. The Office admits that the present application discloses that targeting these exemplary genes with RNA interference would treat these conditions. The Office's contention is that the methods disclosed in the present application do not "fit" with what is allegedly known about the mechanisms behind the conditions. However, none of the references suggest that inhibiting the expression of the genes with RNA interference would exacerbate the condition or make it worse. The references cited by the Office are not sufficient to reasonably question the enablement of the presently claimed invention.

The Office alleges that the cited references do not teach or suggest any link between inhibiting, for example, PDE6B and the treatment of the conditions listed in claim 99. The absence of corroborating evidence outside of the present application is not sufficient to question the enablement of the claim. The M.P.E.P. § 2164.04 states

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

The court further explained "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to *back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement*. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." (M.P.E.P. § 2164.04 (quoting *In re Marzocchi* 439 F.2d at 224, 169 USPQ at 370)). (emphasis added). Here, the Office has not backed up any of its assertions with any acceptable evidence or reasoning. The absence of other references showing a correlation does not prove that the

presently claimed invention is not enabled. In contrast the present specification states that these conditions can be treated as described. Without sufficient evidence the Office must withdraw its enablement rejection.

Accordingly, claim 99 is enabled because the Office has not provided sufficient evidence to reasonably question the enablement of the claim. In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 1, 4-6, 94, 95, 97, and 98 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by King (US 20020165158 A1). Applicants respectfully disagree, but solely in order to further prosecution, Applicants have amended claim 1 by incorporating the elements of claim 99. As admitted by the Office, the King reference fails to anticipate claim 99, which depended upon claim 1. Accordingly, the King reference fails to anticipate the claims.

Claims 4-6, 95, and 97 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Tolentino *et al.* (U.S. Patent No. 7,148,342). Applicants respectfully disagree, but solely in order to further prosecution, Applicants have amended claim 1 by incorporating the elements of claim 99. As admitted by the Office the Tolentino reference fails to anticipate claim 99, which depended upon claim 1. Accordingly, the Tolentino reference fails to anticipate the claims.

In view of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 102 be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 1, 4-6, 9, 16, 94, 95, 97, and 98 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Robinson et al. (U.S. Patent No. 5,814,620) in view of Tuschl et al. (U.S. Patent Publication No. 2004/0259247 A1); Bass (2001) Nature 411:428-429; and Pardridge (U.S. Patent Publication No. 2002/0054902). Applicants respectfully disagree, but solely in order to further prosecution, Applicants have amended claim 1 by incorporating the elements of claim 99. As admitted by the Office, the combination of the cited references fails to

render claim 99 obvious, which depended upon claim 1. Accordingly, the references fails to render the amended claims obvious.

In view of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 103 be withdrawn.

Conclusion

Applicants respectfully assert that the claims are in condition for allowance. Accordingly, a Notice of Allowance is earnestly requested. Applicant has timely filed this response. In the event that an additional fee is required for this response, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-0436.

Should the Examiner have any questions or comments, or need any additional information from Applicants' attorney, he is invited to contact the undersigned at his convenience.

Respectfully submitted,



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